

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Cardiac Science, Inc.,
a Delaware Corporation,

Civil No. 03-1064 (DWF/RLE)

Plaintiff,

v.

**MEMORANDUM
OPINION AND ORDER**

Koninklijke Philips Electronics N.V.,
a Netherlands corporation d/b/a
Royal Philips Electronics;
Philips Electronics North America
Corporation, a Delaware corporation; and
Philips Medical Systems North America
Company, a Delaware corporation,

Defendants;

and

Koninklijke Philips Electronics N.V.,
a Netherlands corporation; and
Philips Electronics North America
Corporation, a Delaware corporation,

Counter Claimants,

v.

Cardiac Science, Inc.,
a Delaware corporation,

Counter Defendant.

Bruce E. Black, Esq., David K. Tellekson, Esq., Heather C. Wilde, Esq., James E. Hanft, Esq., and Robert L. Jacobson, Esq., Darby & Darby PC; and Dennis C. Bremer, Esq., and Matthew J. Goggin, Esq., Carlson Caspers Vandenburg & Lindquist, counsel for Plaintiff and Counter Defendant.

Adam R. Steinert, Esq., Eugene L. Chang, Esq., Gary Serbin, Esq., John M. DiMatteo, Esq., Kimberly May Rosen, Esq., Spyros S. Loukakos, Esq., Steven H. Reisberg, Esq., Willkie Farr & Gallagher LLP; and Lawrence J. Field, Esq., David D. Axtell, Esq., Douglas R. Boettge, Esq., and Harold D. Field, Jr., Esq., Leonard Street and Deinard, PA, counsel for Defendant and Counter Claimant.

Introduction

This matter came before the Court on June 6, 2006, pursuant to a Motion for Summary Judgment of Invalidity of United States Patent Numbers 5,645,571 (the “571 Patent”) and 5,797,969 (the “969 Patent”) brought by Defendants Koninklijke Philips Electronics N.V., Philips Electronics North America Corporation, Koninklijke Philips Electronics N.V., and Philips Electronics North America Corporation (collectively, “Philips”). For the reasons set forth below, Philips’ motion is granted.

Background

“Section 102(b) of the Patent Act of 1952 provides that no person is entitled to patent an ‘invention’ that has been ‘on sale’ more than one year before filing a patent application.” *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 57 (1998); 35 U.S.C. § 102(b). The issue before the Court relates to Philips’ assertions that Plaintiff Cardiac Science, Inc. (“Cardiac Science”) violated 35 U.S.C. § 102(b) by commercializing and/or actually selling automated external defibrillators (“AEDs”) that are described by the ‘571 and ‘969 Patents more than one year prior to the filing of those two patents’ applications.

In late 1991, Byron Gilman first conceived the idea of automatic self-testing in an AED. (Gilman Dep. at 12.) Gilman and several other people founded the corporation

Survivalink in 1992 to design and sell AEDs, including Gillman's conception.

Survivalink is the predecessor to Cardiac Science.

On January 31, 1994, Survivalink submitted a 510(k) application to the FDA seeking clearance to market and sell its Vivalink AED in the United States.

Undisputedly, this FDA application described the same functional features that were later described in the '571 and '969 Patents. (*See, e.g.*, Decl. of David D. Axtell in Supp. Of Philips' Mem. of Law in Supp. of its Mo. For Summ. J. of Invalidity of U.S. Patent Nos. 5,645,571 and 5,797,969 ("Axtell Decl.") Ex. 3 at CSI 51630, 51659 (Fig. 1); Axtell Decl. Ex. 1 at Figs. 1, 2, and 6.) Kenneth Olson, Survivalink's Chief Technical Officer, stated that the FDA application was more detailed than the '571 and '969 Patents and that the '571 and '969 patent applications could have been filed in January 1994, at the same time the FDA application was filed. (Axtell Decl. Ex. 7 at 188:5-11; 183:9-12.) At his deposition, Olson also testified that all of the elements of the claims 1, 5, 7, and 20 of the '571 Patent and claims 1, 10, and 15 of the '969 Patent were in the Vivalink AED when the FDA application was submitted. (*Id.* at 177:5-182:10; 183:13-184:22; 186:2-24.)

In June 1994, Survivalink signed a Distribution Agreement (the "Distribution Agreement" or "June 1994 Distribution Agreement") with Ferno-Washington, an international distributor of medical devices located in Ohio. (Axtell Decl. at ¶ 5, Ex. 4.) Pursuant to the Distribution Agreement, Ferno-Washington became the exclusive worldwide distributor of the Vivalink AED for a term of three years, so long as Ferno-Washington met or exceeded the sales goals set out in Exhibit B to the Distribution Agreement. (*Id.* at F000525.) The Distribution Agreement also stated that Survivalink

would deliver all products sold to Ferno-Washington “FOB carrier at the plant” and that “[t]itle to, and all risk or loss of damage or casualty to such products [would] pass to Ferno-Washington upon delivery.” (*Id.* at F000523.) Further, Ferno-Washington agreed to the transfer prices set out in Exhibit C to the Distribution Agreement. (*Id.*) These prices were initially set at \$1450 per Vivalink AED, but Survivalink reserved the right to alter the price upon sixty days’ notice. (*Id.*) According to the terms of the Distribution Agreement, Survivalink also agreed to accept Ferno-Washington’s standard purchase order form. (*Id.*)

According to Cardiac Science, at the time they entered into the Distribution Agreement, Survivalink and Ferno-Washington understood that Survivalink did not actually have a product for sale because Survivalink was still testing and working on the AED’s design and because the AED had not been approved for marketing in the United States by the FDA. (Decl. of Byron Gillman Opposing Philips’ Mo. for Summ. J. of Invalidity of U.S. Patent Nos. 5,645,571 and 5,797,969 (“Gilman Decl.”) at ¶¶ 8-9; Decl. of Joe Bourgraf Opposing Philips’ Mo. for Summ. J. of Invalidity of U.S. Patent Nos. 5,645,571 and 5,797,969 (“Bourgraf Decl.”) at ¶¶ 6-7.)

In a Report to Shareholders for the Six Months Ended June 30, 1994, Survivalink reported to its shareholders that:

The Company has entered into a distribution agreement with Ferno-Washington to market and sell the VivaLink AED through its worldwide distribution network. Ferno is a manufacturer of emergency equipment with a reputation of providing high quality products. Of interest to SurVivaLink, is that they have a strong worldwide distribution network which sells a variety of emergency products to intended customers. Our

relationship with Ferno has provided a cost effective method to reach the wide and diversified first responder market.

(Axtell Ex. 5 at CSI 031475.) Byron Gilman, Survivalink's CEO, also reported to the shareholders that before June 30, 1994, Survivalink had sold nine fully-functional Vivalink AEDS to Ferno-Washington. (Axtell Decl. Ex. 9 at 136:24-138:9; 150:4-151:25.) Cardiac Science contends, however, that Survivalink merely provided demonstration units for its AEDs to its network of independent distributors in Canada, but that these demonstration units were non-functional. Cardiac Science asserts that Canadian sales representatives marketed these AEDs in Canada and reported the marketing efforts to Survivalink shareholders in the August 30, 1994 report.

Cardiac Science also asserts that it was only after the FDA approved the AED for sale in the United States on February 9, 1995, that Survivalink conducted its first successful test of the product on a live animal. Cardiac Science contends that Survivalink did not accept purchase orders for the product until sometime after this testing was completed and that it shipped the first AEDs on or about March 28, 1995. Cardiac Science has not set forth how the products that were tested initially on animals differed from the products that were shipped in March 1995.

The '571 and '969 patent applications were filed on August 9, 1995, and August 8, 1995, respectively. Although the '571 and '969 Patents undisputedly describe the Vivalink AED that was set forth in the FDA application and the Distribution Agreement, Gilman did not disclose the June 1994 Distribution Agreement with Ferno-Washington to the Patent Office when the '571 and '969 Patents were filed. (*Id.* at 142:25-143:19.)

Discussion

I. Standard of Review

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The court must view the evidence and the inferences that may be reasonably drawn from the evidence in the light most favorable to the nonmoving party. *Enter. Bank v. Magna Bank of Missouri*, 92 F.3d 743, 747 (8th Cir. 1996). However, as the Supreme Court has stated, “[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed ‘to secure the just, speedy, and inexpensive determination of every action.’” *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Enter. Bank*, 92 F.3d at 747. The nonmoving party must demonstrate the existence of specific facts in the record which create a genuine issue for trial. *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials but must set forth specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986); *Krenik*, 47 F.3d at 957.

II. On-Sale Bar

As noted above, pursuant to 35 U.S.C. § 102(b), no person is entitled to patent an invention that has been “on sale” more than one year before filing a patent application.

Pfaff, 525 U.S. at 57 (1998); 35 U.S.C. § 102(b).¹

Determining whether the patent is invalid under § 102(b) requires a determination as to whether, more than one year before the application for U.S. patent, the invention was both ready for patenting and the subject of a commercial offer for sale. *Pfaff*, 525 U.S. at 67; 35 U.S.C. § 102(b). An invention is considered “ready for patenting” if there is proof of a reduction to practice before the critical date (in this case, August 1994) or “proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.”² *Pfaff*, 525 U.S. at 67–68. An invention has been “offered for sale” pursuant to § 102(b) if there has been an “offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration)” *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001).

The issue of whether a patent claim is invalid under § 102(b) is a question of law based on underlying questions of fact. *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d

¹ A patent is invalid if “the invention was patented or described in a printed publication in this or a foreign country or in public use or sale in this country, more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b).

² Based on Olson’s deposition testimony, the AEDs at issue were ready for patenting in January 1994.

1253, 1257 (Fed. Cir. 2001). The party challenging the patent's validity bears the burden of proving, by clear and convincing evidence, that "there was a definite sale or offer to sell more than one year before the application for the subject patent, and that the subject matter of the sale or offer to sell fully anticipated the claimed invention." *Group One*, 254 F.3d at 1045–46 (citations omitted).

In its Motion for Summary Judgment, Philips asserts that the AED devices described in the '571 and '969 Patents were (1) ready for patenting and subject to a commercial offer for sale, and, alternately, (2) the subject of an actual sale, more than one year prior to the application of the patents, thus invalidating the patents. Specifically, Philips first contends that Survivalink violated the on-sale bar by entering into the June 1994 Distribution Agreement with Ferno-Washington to sell the Vivalink AEDs, which were ready for patenting in January 1994. Second, Philips asserts that Survivalink also violated the on-sale bar by actually selling at least nine Vivalink AEDs to Ferno-Washington in June 1994. Both of these events were alleged to have occurred more than one year prior to the filing date of the '571 and '969 Patents.

A. Offer for Sale

Cardiac Science asserts that the June 1994 Distribution Agreement did not constitute a commercial offer for sale. Rather, Cardiac Science contends that the Distribution Agreement was merely an agreement for rights to commercialize or distribute Survivalink's products in the future, if Survivalink later accepted Ferno-Washington's offer to purchase the products. In other words, Cardiac Science contends that the Distribution Agreement merely laid the groundwork in order to later

sell the AEDs. Cardiac Science asserts that the testimony of Gilman and Bourgraf support the notion that Survivalink did not intend for the Distribution Agreement to be an offer for sale of the Vivalink AEDs.

The Court finds that the June 1994 Distribution Agreement constituted a commercial offer for sale that invalidates the ‘571 and ‘969 Patents. The Distribution Agreement unambiguously contains all of the material terms necessary for Ferno-Washington to purchase Vivalink AEDs from Survivalink. Both Ferno-Washington and Survivalink signed the Distribution Agreement. The terms of the contract were laid out and binding on both parties for a three-year term. Specifically, the Distribution Agreement included the price of the AEDs,³ the method of delivery, the warranty, and the method of payment. In addition, the Distribution Agreement required Ferno-Washington to sell a certain number of Vivalink AEDs per quarter to maintain their exclusive distributorship. (Axtell Decl. Ex. 4 at Ex. B.) The June 1994 Distribution Agreement merely required Ferno-Washington to send a purchase order to Survivalink to specify the number of units ordered—a purchase order which Survivalink was bound to accept. Thus, the Distribution Agreement was an “offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration)” *Group One*, 254 F.3d at 1048.

³ The Court finds no merit to Cardiac Science’s assertion that because the price could be changed by Survivalink with sixty days’ notice, the Distribution Agreement lacked a fixed price. Even if the Distribution Agreement was considered not to have a fixed price, it still could qualify as an invalidating offer for sale. *See, e.g., Zacharin v. U.S.*, 213 F.3d 1366, 1370 (Fed. Cir. 2000) (holding that the fact that contract at issue specified no fixed price did not prohibit application of the on-sale bar).

Contrary to Cardiac Science's assertions, the conclusory testimony of Gilman and Bourgraf is not persuasive as to Survivalink's intent at the time the Distribution Agreement was entered into. Gilman and Bourgraf's testimony is contrary to both the clear language of the contract and to Gilman's description of the Distribution Agreement to the Survivalink shareholders as "a distribution agreement with Ferno-Washington *to market and sell* the Vivalink AED" (Axtell Decl. Ex. 5 at CSI031475 (emphasis supplied).) Finally, no legal authority supports Cardiac Science's assertions that because the AEDs had not yet been tested on live animals, they were not actually "on sale."

Given that these devices were ready for patenting in January 1994 and because the Court finds that Survivalink made a commercial offer for sale of the inventions to Ferno-Washington in June 1994, more than a year before filing the '571 and '969 applications, the '571 and '969 Patents are invalid pursuant to 35 U.S.C. § 102(b).

B. Actual Sale

Because the Court finds that the Distribution Agreement was a commercial offer to sell the Vivalink AED, thus invalidating the '571 and '969 Patents, the Court need not address Philips' argument regarding actual sales of the AED.

Accordingly, **IT IS HEREBY ORDERED THAT:**

1. Philips' Motion for Summary Judgment of Invalidity of United States Patent Numbers 5,645,571 and 5,797,969 (Doc. No. 423) is **GRANTED**.

Dated: July 19, 2006

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court